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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,815

10/21/2005

Sumit Roy

3651-1025

6741

466

7590

08/21/2006

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/522,815

Applicant(s)

ROY ET AL.

Examiner

Kathleen Sonnett

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12 and 14-19 is/are rejected.
- 7) ☒ Claim(s) 10-11 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/2/2005, 6/2/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-3, and 5-9, 12, 14-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berreklouw (U.S. 6,524,322) in view of Bolduc et al. (U.S. 6,193,734). Berreklouw discloses a method for interconnection of and fluid communication between two tubular organs via an opening at one end of an end portion of a first organ (4) and an aperture in a side wall of a second organ characterized in passing the end portion through a first passage of a first element (16) until the end portion (24) projects past an end edge of the element, everting the end portion round the end edge, inserting gripping parts (11) of a second element (10) with a second passage in the second organ (2) via the aperture (see Fig. 2 and 3). Berreklouw fails to disclose the gripping parts being capable of being influenced to engage with an edge portion of the aperture by inserting the first element in the second passage and inserting the first element with the everted portion of the first organ in the second passage. Berreklouw instead discloses gripping parts whose configurations are pre-tensioned to face inwardly and can be released with the aid of other instruments or mechanical aids.

However, Bolduc et al. discloses that it is old and well known in the art to have gripping portions in a system for performing an anastomosis surgery that can be influenced to engage with an edge portion of an aperture by inserting a tube inside of the passage within the gripping portions. In particular, tube 16 is inserted inside of element (32) so that gripping portions (30)

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are influenced to engage with an edge portion of an aperture. Berreklouw discloses that it is advantageous to have the inner tube (with gripping portions) of an anastomosis device in a sloping, inwardly facing position when inserted through an aperture so that the stretching of the target vessel around the connection opening is not necessary (col. 6 lines 27-46). Using the teachings of Bolduc et al. to move inwardly facing gripping portions into engagement with the target vessel would simplify the device of Berreklouw as a mechanical aid to release pre-tensioned gripping portions would no longer be necessary. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Berreklouw to include gripping portions that are influenced to engage with an edge portion of the aperture by inserting the first element in the second passage and inserting the first element with the everted portion of the first organ in the second passage.

Regarding claims 2 and 3, the modified device of Berreklouw includes gripping portions like those made obvious by Bolduc in Fig. 7 and 8. When the first element is inserted into the second element (partially inserted), the gripping parts are only influenced once the first element reaches a certain depth within the second element.

Regarding claim 5, Berreklouw discloses bringing support parts (14) of the second element into engagement with the outside of the second organ (2) at the edge portion when the gripping parts are inserted in the aperture (see fig. 3).

Regarding claim 6, the gripping parts are secured into position after they have been brought into engagement with the second organ. In particular, in the modified device of Berreklouw, the gripping portions (11) have a transverse dimension less than that of the aperture and when first element (16) is placed coaxially within second element (10), gripping portions (11) are reconfigured to bend up against the tissue.

Regarding claim 7, modified Berreklouw discloses a device for implementing the method described above comprising a first element and a second element with an axially front portion comprising at least two elongated first fingers (11) which are arranged at intervals along the circumference of a second passage of the second element which comprise main portions (straight portion 12 in Fig. 3) and gripping portions which extend away from the main portions. As modified by Bolduc to include gripping parts that are pushed outward by the insertion of the first element within the second element. The transverse dimension of the radially external terminations of the gripping parts is smaller than the transverse dimension of the aperture when the fingers are relaxed and the front end portion of the first element is arranged for coaxial insertion in the second passage and the front portion via a receiving portion and for exerting a radially outwardly directed force against the main portions, thereby moving the main portions of the gripping parts radially outwards until the transverse dimension between the gripping parts' external terminations is larger than the transverse dimension of the aperture.

Regarding claim 8, the second element comprises at least one second finger (14) that includes a main portion (15) and a support part (14).

Regarding claim 9, element 2, which includes the second finger (14) may be convex (col. 10, lines 62+).

Regarding claim 12, element (15) is now being considered a sleeve-shaped casing which is coaxial with the internal portion and arranged radially outside of it, the internal portion defining a cylindrical annulus (space between 16 and 15). The rear ends of 16 and 15 are attached.

Regarding claim 14, the first element has a shoulder (27) that is arranged to abut against a cooperating portion (15) of the second element for restricting insertion distance.

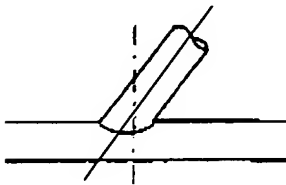
Regarding claim 15, the second element is perforated (col. 9, line 15).

Regarding claim 16, the second element has a rear portion that the examiner is considering flared because rear portion (10) is thicker than portion (11) and so the outer diameter is larger at the rear portion.

Regarding claim 17, the front edge (24) of a first element is located in a first plane and the gripping parts are located in a second plane, the planes forming the same angle with the longitudinal axes of the respective elements (see fig. 3).

Regarding claim 18, the angle formed by the planes with the respective longitudinal axes appears to be at 90 degrees in fig. 3.

Regarding claim 19, see the figure below.



**Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berreklouw in view of Bolduc et al. as applied to claim 1 above and in further view of Whayne (U.S. 6,702,828). The modified invention of Berreklouw discloses the invention substantially as stated above, but fails to disclose applying adhesive at the point of interconnection of the organs.

However, Whayne discloses that it is old and well known in the art to apply adhesives to points of interconnection during anastomosis procedures (col. 18 lines 38-43). Whayne further discloses that adhesives can be used to enhance already formed mechanical bonds (col. 9 line 64-col. 10 line 9). Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Berreklouw to include the step of applying an adhesive at the point of interconnection of the organs as made obvious by Whayne in order to enhance the already formed mechanical bond seen in Fig. 3.

***Allowable Subject Matter***

Claims 10-11 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS  
8/8/2006

  
GLENN K. DAWSON  
PRIMARY EXAMINER